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GW syndromes or symptoms, an	nd factors that may mediate these	relationships. The propo	sed study has f	ive key aims intended to		
address these gaps and enhance i	understanding of illnesses reporte	ed by GW veterans:				
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(2) to assess exposures to environ	onmental toxins and psychosocial	stressors comprehensive	ely and to iden	tify the dimensions of these		
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of GW veterans;				_		
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(5) to examine the mediating ro	le of post-ODS/S factors (e.g., in	strumental and emotional	social suppor	t, general psychological		
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INTRODUCTION: Brief Narrative of Subject, Purpose, and Scope of the Research

Research on Gulf War (GW) illnesses leaves many questions unanswered about diagnostic syndromes of GW illnesses, dimensions of stressor exposures encountered by GW veterans, relations among stressor exposures and GW syndromes or symptoms, and factors that may mediate these relationships. The proposed study has five key aims intended to address these gaps and enhance understanding of illnesses reported by GW veterans:

- (1) to identify and examine dimensions of illnesses and health problems commonly reported by GW veterans;
- (2) to assess exposures to environmental toxins and psychosocial stressors comprehensively and to identify the dimensions of these exposures;
- (3) to examine the extent to which particular types of dimensions of exposure experienced during during deployment and participation in Operation Desert Shield/Desert Storm (ODS/S) are associated with the commonly reported and undefined post-war health problems of GW veterans;
- (4) to clarify how premilitary and predeployment adversities, risk factors, and protective factors affect GW illness outcomes;
- (5) to examine the mediating role of post-ODS/S factors (e.g., instrumental and emotional social support, general psychological functioning, specific comorbid psychiatric disorders, such as posttraumatic stress disorder and depression) on GW illness outcomes.

These aims will be achieved by obtaining in-depth data from a national probability sample of GW veterans, including both men and women in active and reserve components.

These aims will be achieved using a two-phase study design. Phase 1 of this study is a mail survey of a national probability sample of GW veterans, including both men and women in active and reserve components. The goal of this survey is to provide comprehensive probability-based data on issues about the dimensions of Gulf War illnesses, dimensions of exposure to environmental toxins and psychosocial stressors encountered by GW veterans, and relationships between these exposures and GW illness syndromes. These issues as well as factors that may mediate relationships between stressor exposures and GW illnesses will be further examined in Phase 2 of the study, a computer-assisted telephone interview (CATI) conducted with a subsample of mail survey respondents with and without symptoms of GW illnesses.

BODY

This section describes the research activities, accomplishments, and factors delaying completion for Year 2 tasks outlined in the approved statement of work. Plans for Year 3 are also described for each task.

Sampling

Year 2 Activities

- Prepared a revised sampling design summary to describe the current sampling procedures being implemented.
- ♦ Thoroughly reviewed the data set documentation for the CCEP and DS/S data sets and identified the specific variables available that would motivate our sampling methodology. Prepared detailed instructions for DMDC to assist in sample frame construction.
- ♦ Used the DS/S and the public use CCEP files in the development of a stratified systematic sample design with eight symptom levels or stratification levels.
- ♦ Conducted a preliminary optimal allocation of a sample of approximately 10,000 over the eight levels of stratification. This optimization was preliminary because the GWI symptom rates that we derived were based on fairly general questionnaire variables from the public use CCEP. More specific statistical analyses will be conducted next year on a more detailed version of the CCEP.
- ♦ Conducted frequency analyses on CCEP variables. Used variables for ICD-9 diagnostic codes, constructed summary variables to identify proportion of sample reporting comparatively high rates of symptoms. Plan to use a subset of these variables with full CCEP sample to estimate optimal rates to sample veterans who have and have not participated in the CCEP for participation in mail survey.

Year 3 Plans

- ♦ Continue working with DMDC in the construction of the sampling frame of GW military personnel.
- Complete the explicit stratification of the sampling frame.
- ♦ Conduct the final optimal allocation of the sample of approximately 10,000 to the explicit strata.
- ♦ Select the sample of military personnel who are selected to participate in the mail health status questionnaire component of the study.
- Compute the sampling weights, which are the inverses of the selection probabilities.

- ♦ Adjust the personnel respondent sample for questionnaire non-response.
- ♦ Document the sample design and the sample weighting procedures used.

Survey Questionnaire Development

Year 2 Activities

- Finalized items and format of Phase 1 mail survey prior to pilot testing.
- ♦ Developed consent form and procedures for pilot test of mail survey.
- Revised mail survey following pilot test in an effort to shorten while including additional items addressing domains of particular concern to pilot participants (e.g., eliminated items assessing constructs more appropriately evaluated in Phase 2 follow-up interview, enhanced assessment of exposure to environmental toxins).
- ♦ Formatted mail survey for printing by National Computer Systems (NCS) (e.g., developed cover graphic, had survey reviewed by professional editor). (A copy of the current version of the survey is provided in Appendix A.)
- ♦ Developed consent form for mail survey as well as informational brochure to serve as lead letter and related survey materials. (See Appendix B.)
- ♦ Negotiated subcontract with NCS for printing, mailing, and processing scanned survey forms. A draft version of the survey in a scannable format should be ready for proofing by October 30.
- ♦ Conducted literature searches of Medline and PsycInfo databases in preparation for development of Phase 2 follow-up interview and to determine optimal selection criteria for that interview. (Bibliography is provide in Appendix C.)

Year 3 Plans

- ♦ Work with NCS to finalize scannable version of mail survey and related materials.
- ♦ Determine optimal selection criteria for Phase 2 follow-up interview.
- ♦ Continue development of instrumentation for Phase 2 follow-up interview.
- ♦ Program and test instrumentation and related procedures Phase 2 follow-up interview

Data Collection

Year 2 Activities

♦ Conducted pilot test of Phase 1 questionnaire.

Year 3 Plans

- ♦ Coordinate with NCS for the mail survey.
- ♦ Conduct tracing operations to obtain addresses for veterans who cannot be located using mailing address from IRS.
- ♦ Collect data for the mail survey.
- ♦ Pilot test and begin data collection for Phase 2 follow-up interview.

Clearances

Year 2 Activities

- ♦ Obtained approval from National Institute for Occupational Safety and Health (NIOSH) to access address data files obtained by NIOSH from the Internal Revenue Service through an Interagency Agreement under Internal Revenue Code Section 6103 (m)(3). The addresses received will be used to locate individuals for the survey and therefore solve the problem of missing addresses in DMDC files noted in the Year 1 annual report. Having this address file also should substantially decrease time required for tracing activities.
- ♦ Had protocol reviewed by DoD personnel to determine clearances needed for study. Obtained documentation that studies conducted under this grant do not require OMB review and are not subject to DoD8910.1-M. (See Appendix D.)
- ♦ Obtained clearances from Duke and RTI Institutional Review Boards (IRB) for full implementation of mail survey. (See Appendix E.)
- Obtained clearances from Duke and RTI IRBs for amendments to protocol for mail survey made to address issues raised in USAMRMC Human Subjects Review. (See Appendix E.)
- Obtained Human Subjects approval for mail survey from USAMRMC. (See Appendix D.)
- Obtained clearance for DMDC to continue assistance with sampling task.

Year 3 Plans

♦ Obtain IRB clearances for pilot test of Phase 2 follow-up interview.

- ♦ Obtain IRB and USAMRMC clearances for full implementation of Phase 2 follow-up interview.
- Obtain IRB clearance (annual review) for continued work on mail survey (e.g., processing and analyzing survey data).

Project Schedule

Year 2 Activities

As noted in our first year annual report, the study experienced a delay of several months due to OPRR/NIH suspension of all research activities involving human subjects at DUMC. We revised our study schedule to account for this delay and anticipated fielding the survey data collection effort by the end of the sixth month of year 2. However, in year 2 we encountered a series of delays associated with obtaining DoD clearances for the study. Details are provided in the bulleted items that are listed below. We have discussed with our USAMRMC project officer, Major John Stuart and DUMC grants officer, Ms. Amy Barbee, the option of requesting a 6-month to one-year extension of the project during year 3. Both indicated their support for such a request. On 9/15/00 we received final DoD clearance to proceed with the project.

- ♦ 4/4/00-4/30/00: On 4/4/00, RTI co-principal investigator, Dr. Robert Bray, sent an e-mail message to Mr. Tim Elig at DMDC requesting clarification of appropriate procedures for review of study by DMDC. On 4/11 Dr. Bray and key RTI project staff participated in a conference call with Mr. Elig in an effort to clarify this approval process. Mr. Elig put us in contact with James A. White, DoD internal Reports Control who concluded that the grant was not subject to the provisions of DoD 8910.1 1-M "DoD Procedures for Management of Information Requirements" and provided documentation to this effect via e-mail on 4/11. Mr. Elig also put us in contact with Bob Cushing, DoD Clearance Office, who after requesting and reviewing selected study materials, concluded that OMB review and approval was not required. (Documentation received via e-mail 4/13.) Throughout April there were additional communications with Mr. Elig and associated staff regarding the appropriate approval procedures for the study.
- ♦ 5/3/00-5/23/00: On 5/3/00, the PI, Dr. Fairbank, contacted the USAMRMC contract representative for study, Major John Stuart, in an effort to clarify the approval process. At this time, MAJ Stuart offered to look into and facilitate the approval process. In response to his efforts, on 5/9, Catherine Smith at USAMRMC sent Dr. Fairbank an e-mail indicating that the protocol for DAMD17-98-8662 had been reassigned to her for review of human subjects protection issues. In this message, Ms. Smith requested documentation of local IRB approval for the survey and related materials (e.g., a copy of the survey and accompanying consent letter). These materials were sent to Ms. Smith on 5/12/00.

In his efforts to facilitate the approval process, on 5/8 MAJ Stuart also contacted Mr. Mike Dove at DMDC to request continued support from DMDC with the sampling task for the mail survey. Mr. Dove (on 5/8) indicated that in order to continue work on the

- study his office needed a letter from the contract officer, Major John Stuart endorsing the study sent with a statement of work and all relevant clearances.
- ♦ 5/24/00-6/21/00: On 5/24/00 Fairbank received an e-mail message from Ms. Smith indicating that an review of the study had been conducted by COL Julie Zadinsky, Acting Chair, Human Subjects Review Board who was requesting submission of a revised protocol as well as additional information regarding approval for active duty personnel to be involved in this research. On 6/6 Dr. Fairbank sent the requested information (i.e., a full USAMRMC Protocol for Research Involving Human Subjects and supporting documentation) to Ms. Smith.
- ♦ 6/22-7/31: On 6/22 Dr. Fairbank received from Ms. Smith an e-mail message that included a Memorandum of Record summarizing recommendations from the USAMRMC Human Subjects review of these materials. Ms. Smith's message indicated that the study would only receive approval once the protocol and consent letter were revised in accordance with the memorandum. The primary procedural issue identified in the memo pertained to USAMRMC legal opinion (offered by CPT Maleson) that it was not appropriate for active duty military personnel to receive any incentive for participating in the study. (In the 6/6 protocol all participants who returned a completed survey were to be entered into a drawing for several cash prizes.) Additionally, the memorandum requested further documentation of approval of consent procedures from the local IRBs. Subsequently, Dr. Fairbank contacted CPT Maleson in an effort to clarify military regulations regarding incentives for active duty personnel. Dr. Fairbank and CPT Maleson continued corresponding about this issue through 7/31 at which point a decision was made to revise the study procedures so that only participants who were no longer on active duty at the time of data collection would be eligible for the prize drawing.
- ♦ 8/1/00-9/13/00: On 8/14/00 Dr. Fairbank sent Ms. Smith a revised USAMRMC Human Subjects Protocol and related study materials intended to address the recommendations made in the Memorandum of Record summarizing the prior USAMRMC Human Subjects Review. On 8/15 Ms. Smith sent Dr. Fairbank an e-mail message indicating that the revisions were satisfactory, but that the study could not be approved until after the USAMRMC received approval for these revisions from Duke and RTI's IRBs. Requests for approval for the amended protocols were submitted to the local IRBs; approval from both the Duke and RTI IRBs was received on 9/13.
- ♦ 9/15/00: Dr. Fairbank received from Ms. Smith notification that the Phase 1 mail survey had received approval from the USAMRMC Human Subjects Review Board.
- ♦ 9/16/00-9/30/00: In an effort to resume the process of obtaining approval from DMDC for continued work on the study, on 9/18, Dr. Fairbank sent MAJ Stuart a revised work plan for the sampling task and copies of all clearances for the study. On 9/26/00 MAJ Stuart sent these materials along with the requested letter of support for the study to Mike Dove at DMDC. (On 10/2/00 Mr. Mike Dove contacted Dr. Fairbank about resuming work on the study. Relevant issues were discussed on 10/6 in a conference call and we are currently awaiting the requested sample files.)

Year 3 Plans

♦ Submit revised study time line and request for project extension (6 months - 1 year) to USAMRMC grants officer.

KEY RESEARCH ACCOMPLISHMENTS

This section of the report focuses on "key research accomplishments emanating from the research." This project is just going into the field at the end of Year 2 and does not yet have accomplishments emanating from the research to report.

REPORTABLE OUTCOMES

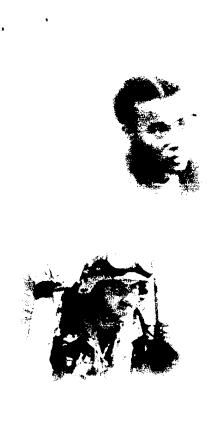
This sections of the report summarizes the results of the completed research. There are not reportable outcomes given that this project is still in the implementation phase.

APPENDICES

The report includes five appendices—Appendix A: Gulf War Veterans Health Survey, Appendix B: Survey consent letter and other study materials, Appendix C: Working bibliography on Gulf War illnesses, Appendix D: Clearances from Military, Appendix D: Clear from Duke University Medical Center and Research Triangle Institute IRBs.

APPENDIX A

Gulf War Veterans Health Survey (Draft)



The Gulf War Veterans Health Survey

Conducted by:

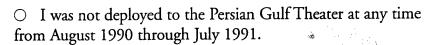
Duke University Medical Center The Research Triangle Institute



The second second

The purpose of this questionnaire is to find out more about the health of people who were deployed to the Persian Gulf Theater at any time from August 1990 through July 1991.

If you were not deployed to the Persian Gulf Theater at all during that time period, please use a pencil to darken the circle below and return the questionnaire now in the postage-paid return envelope provided. We do not need you to answer any of the questions, but it is very important that you return the questionnaire to us so that we will know that you were not deployed during that time.



If you were deployed to the Persian Gulf Theater at any time from August 1990 through July 1991, please complete the questionnaire.

Gulf War Veterans Health Survey Instructions

- Pay careful attention to the *time frames* in questions and in the instructions that appear before some groups of questions. The time frames change from section to section of the questionnaire. For example, some questions will refer to your experiences during the time you were in the Persian Gulf, and other questions will refer to other time periods in your life.
- Most questions provide a set of answers. Read *all* of the printed answers before making your choice. If none of the printed answers exactly applies to you, mark the circle for the one answer that *best* fits your situation.
- Use only a soft-lead pencil (such as a #2) to complete this questionnaire.
- Make *heavy black marks* that *fill* the circle of your answer.

CORRECT MARKS

■ INCORRECT MARKS

② ③ ⊕ ⊙

- Completely erase any answers you wish to change.
- Do *not* make any stray marks anywhere in this booklet.
- Sometimes you will be asked to "Choose an answer *on each line*," for example, when you are asked, "Please choose 'Yes' or 'No' for each question." For these questions, record an answer to <u>each part</u> of the question, as shown:

EXAMPLE:

Has a health care provider ever told you that you had any of the following

■ For many questions, you will be asked to "Please choose the *best* answer." You should mark only *one* circle for your answer in the column below the question, as shown:

EXAMPLE:

In general, would you say your health is:

O EXCELLENT

VERY GOOD

O Good

O Fair

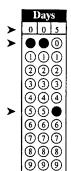
O Poor

1. From August 1990 through July 1991, in which area(s) of the Persian Gulf Theater did you serve? (Please choose "Yes" or "No" for each area.)	4. From August 1990 through July 1991, about how long did you spend in the area you chose in Question #3? (Please choose the best answer.)
A. IRAQ O O O B. SAUDI ARABIA O O C. KUWAIT O O D. TURKEY O O E. OMAN O O F. BAHRAIN O O G. QATAR O O I. THE UNITED ARAB EMIRATES O O I. THE GULF OF OMAN O O L. THE GULF OF ADEN O O M. OTHER O O 2. During the 12 months from August 1990 through July 1991, about how much time did you spend in the Persian Gulf Theater? (Please choose the best answer.) O LESS THAN 3 MONTHS O 3 MONTHS BUT LESS THAN 6 MONTHS O MORE THAN 9 MONTHS 3. From August 1990 through July 1991, in which area of the Persian Gulf Theater did you spend most of your time? (Please choose the best answer.) O IRAQ O SAUDI ARABIA O KUWAIT O TURKEY O OMAN BAHRAIN O QATAR O THE UNITED ARAB EMIRATES O THE GULF OF OMAN THE GULF OF ADEN THE ARABIAN SEA O OTHER	 ○ LESS THAN 3 MONTHS ○ 3 MONTHS BUT LESS THAN 9 MONTHS ○ 6 MONTHS BUT LESS THAN 9 MONTHS ○ MORE THAN 9 MONTHS 5. During the entire time you have served on Active Duty, in the Reserves, or in the National Guard, about how much total time have you spent in the Persian Gulf Theater? (Please choose the best answer.) ○ LESS THAN 3 MONTHS ○ 3 MONTHS BUT LESS THAN 6 MONTHS ○ 6 MONTHS BUT LESS THAN 9 MONTHS ○ 9 MONTHS BUT LESS THAN 1 YEAR ○ 1 YEAR BUT LESS THAN 2 YEARS ○ MORE THAN 2 YEARS 6. From August 1990 through July 1991, in which component of the Military did you serve? (Please choose the best answer.) ○ ACTIVE ARMY (USA) ○ ARMY NATIONAL GUARD (ARNG) ○ ARMY RESERVE (USAR) ○ ACTIVE ARY (USN) ○ NAVAL RESERVE (USNR) ○ ACTIVE AIR FORCE (USAF) ○ AIR NATIONAL GUARD (ANG) ○ AIR FORCE RESERVE (USAFR) ○ ACTIVE MARINE CORP (USMC) ○ MARINE CORPS RESERVE (USMCR)
	1

➤ If you are asked to give numbers for your answer, please complete the grid as shown below:

EXAMPLE: Think about any illnesses you may have had in the past 12 months. How many days were you unable to perform your job because of an illness in the past 2 months?

- First, enter the number of days in the boxes. Use <u>all three</u> boxes. Write <u>ONE</u> number in each box.
- Always write the last number in the <u>right-hand box</u>. Fill in any <u>unused</u> boxes with <u>zeroes</u>. For example, an answer of "5 days" would be written as "005."
- Then, blacken the matching circle below each box.



7. What date did you first begin serving in the Persian Gulf Theater, even if it was before August 1990?

Month		Year
	Ì	
@@@@@@@@@@@ @@@@@@@@@@@		

8. What date did you stop serving in the Persian Gulf Theater, even if it was after July 1991, (that is, what was the end date of your last deployment to the Persian Gulf)?

Month	Ye	ar
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(D)(D)	(D)	8
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99	(9)	9

Think of the <u>first time</u> you were deployed to the Persian Gulf Theater during the time <u>from August 1990 through July 1991</u>. The next several questions refer to the time of that deployment, which will be called "<u>the time of your first deployment.</u>" Please remember that if you were deployed to the Persian Gulf Theater prior to August 1990 or after July 1991, we do not want you to answer regarding that time period.

9. At the time of your first deployment (that is, during the period from August 1990 through July 1991), what was your pay grade? (Please choose the best answer.)

Enlisted	<u>Officer</u>
O E-1	O TRAINEE
O E-2	O W1-W5
O E-3	O O-1 or O-1E
○ E-4	O O-2 or O-2E
○ E-5	O O-3 or O-3E
○ E-6	O O -4
○ E-7	O O-5
○ E-8	O O-6
○ E-9	О О-7 то О-10

10. At the time of your first deployment (that is, during the period from August 1990 through July 1991), which of the following categories best describes the military responsibilities you had? (Please choose the best answer.)

Please refer to the double-sided handout labeled "Job Category Examples Handout" that came with this survey for examples of different job categories.

ENLISTED

- O INFANTRY, GUN CREW, OR SEAMANSHIP SPECIALIST
- O ELECTRONIC EQUIPMENT REPAIR SPECIALIST
- O COMMUNICATIONS OR INTELLIGENCE SPECIALIST
- O HEALTH CARE SPECIALIST/TECHNICIAN
- O OTHER TECHNICAL OR ALLIED SPECIALIST
- O FUNCTIONAL SUPPORT AND ADMINISTRATION
- O ELECTRICAL OR MECHANICAL EQUIPMENT REPAIR SPECIALIST
- O CRAFTSMAN
- O SERVICE AND SUPPLY HANDLER
- OTHER (E.G., OFFICER CANDIDATES, STUDENTS, SPECIAL DUTIES)

OFFICER

- General Officer, Executive Officer, or Commanding Officer
- O TACTICAL OPERATIONS OFFICER

(continued on next page)

	O INTELLIGENCE OFFICER	Yes No	<u>o</u>
	O Engineering or Maintenance Officer	F. Diabetes or high blood sugar	
	O Scientist, Professional, or Staff Support	G. HEART ATTACK OR OTHER SERIOUS	
	(NOT INVOLVED IN HEALTH CARE)	HEART TROUBLE)
	Health Care Provider	H. Severe hernia or rupture	
	O Administrator or Operational Support	I. SEVERE KIDNEY OR LIVER DISEASE	
	O Supply, Procurement, or Allied Officer	J. Lupus, thyroid disease, or other	
	OTHER (E.G., STUDENTS, TRAINEES, BILLET	AUTOIMMUNE DISORDERS)
	DESIGNATORS)	K. MULTIPLE SCLEROSIS, EPILEPSY,	
		OR OTHER NEUROLOGICAL DISORDERS O O)
11.	At the time of your first deployment, what	L. CHRONIC STOMACH OR GALL BLADDER	
	was the <u>highest</u> level of education you had	TROUBLE)
	completed? (Please choose the best answer.)	M.Stroke	
	·	N. Ulcer	
	O HAD NOT YET GRADUATED FROM HIGH SCHOOL	O. CANCER OR A MALIGNANT TUMOR	
	O GED OR ABE CERTIFICATE	OF ANY KIND)
	O HIGH SCHOOL GRADUATE	P. OTHER MAJOR HEALTH PROBLEMSOO	ı
	O TRADE OR TECHNICAL SCHOOL GRADUATE		
	O SOME COLLEGE BUT NOT A 4-YEAR DEGREE	14. In the past 6 months, have you had persisten	nt
	 4-year college degree (BA, BS, or equivalent) Some graduate or professional study but no 	or recurring problems with (Please choose	
	GRADUATE DEGREE	"Yes" or "No" for each health problem.)	
	O GRADUATE OR PROFESSIONAL DEGREE		
	O GRADUATE OF PROFESSIONAL DEGREE	Yes No	:
12	At the time of your first deployment, what	A. HOT OR COLD SPELLS, FEVER,	
14.		SWEATS AT NIGHT, OR SHAKING CHILLSOO B. MOUTH SORESO	
	was your marital situation? (Please choose the	C. Inflammation or redness of your eyes	
	best answer.)	(PINK EYES)	
	O NOT MARRIED, BUT LIVING AS MARRIED	D. UNEXPECTED HAIR LOSS	
	O Married	E. Sore throat or irritation	
	O SEPARATED AND NOT LIVING AS MARRIED	F. PAIN OR ACHES IN MORE THAN ONE JOINTOO	
	O DIVORCED AND NOT LIVING AS MARRIED	G. BACK PAIN	
	O WIDOWED AND NOT LIVING AS MARRIED	H. JOINT STIFFNESS	
	O Single, never married, and not living as married	I. Muscle tension, aches, soreness,	
	•	OR STIFFNESS	
The	next group of questions ask about a number of	J. FEELING WEAK IN PARTS OF YOUR BODYOO	
	lth problems or concerns a person might have.	K. Tender or painful lymph glands	
We ·	would like to know whether or not you have	UNDER YOUR ARMS OR IN YOUR NECKOO	
	erienced each of these problems during the <u>past</u>	L. A FEELING OF BODILY DISCOMFORT	
<u>5 m</u>	onths.	AFTER EXERTION	
		M. Numbness or tingling in parts	
13.	In the past 6 months, have you experienced	OF YOUR BODYOO	
	any of these health problems? (Please choose	N. Loss of hearing or ringing in your ears	
	"Yes" or "No" for each health problem.)	O. Tremors or shaking	
	•	P. Double vision, when you see 2 images,	
	Yes No	NOT CORRECTABLE BY GLASSES	
	A. Severe arthritis, rheumatism,	Q. SEIZURES OR CONVULSIONS	
	OR OTHER BONE OR JOINT DISEASES	R. Any headaches	
	B. Severe asthma, bronchitis,	S. HEART PALPITATIONS, POUNDING	
	EMPHYSEMA, OR OTHER LUNG PROBLEMSOO	OR RACINGOO	
	C. AIDS	T. Pains in your heart or chest	
	D. BLINDNESS OR SEVERE VISUAL OR	U. FAINTNESS, LIGHTHEADEDNESS	
	HEARING IMPAIRMENT	OR DIZZINESS	
	E. HIGH BLOOD PRESSURE OR HYPERTENSIONO		
		(continued on next po	age)

		Yes	No		<u>Yes</u>	<u>No</u>
	V.	TROUBLE SWALLOWING	0	M. HAVE YOU HAD PROBLEMS WITH FEELING		
	W.	Nausea or an upset stomach		CONFUSED OR DISORIENTED IN PLACE OR		
		(OTHER THAN DURING PREGNANCY)O	0	TIME? (FEELING CONFUSED ABOUT WHERE		
	X.	•		YOU ARE, WHO IS AROUND, OR NOT		
		(OTHER THAN DURING PREGNANCY)O		KNOWING WHAT DAY IT IS)	\circ	\circ
	Y.	Vomiting (other than		· · · · · · · · · · · · · · · · · · ·	.0	.0
	1.			N. HAVE YOU BEEN HAVING DIFFICULTY		
	7	DURING PREGNANCY)	0	UNDERSTANDING WHAT YOU READ, EVEN		
	<i>L</i> .	Frequent diarrhea (more than		WHEN YOU ARE PAYING ATTENTION TO	_	_
		3 WATERY STOOLS PER DAY)	0	WHAT YOU ARE READING?	.0	.0
	AA.	ABDOMINAL PAIN		O. HAVE YOU BEEN BOTHERED BY A COUGH	_	_
		(OTHER THAN WHEN MENSTRUATING)O		WHEN YOU DID NOT HAVE A COLD OR FLU?	.0	.0
		CONSTIPATION	l l	P. HAVE YOU BEEN CONGESTED OR DID YOU		
		Frequent or painful urinationO	0	BRING UP MUCOUS OR PHLEGM WHEN YOU		
	DD.	ANY TENDENCY TO BRUISE OR BLEED		DID NOT HAVE A COLD OR FLU?	.0	.0
		EASILY (INCLUDING NOSE BLEEDING) O	0	Q. Has your chest sounded wheezy or		
	EE.	SKIN REDNESS OR A SKIN RASH	0	WHISTLING WHEN YOU DID NOT HAVE A		
	FF.	Dryness or scaling of your skin O	0	COLD OR FLU?	.0	.0
	GG.	BLISTERS, OPEN SORES, OR SKIN		R. HAVE YOU HAD AN ATTACK OF WHEEZING		
		ULCERS	0	THAT HAS MADE YOU FEEL SHORT OF		
	HH.	ERUPTIONS OF HIVES OR WELTS		BREATH?	.0	.0
		ON YOUR SKIN	0	S. HAS THERE BEEN AN OCCASION WHEN		
	Π.	PERSISTENT SENSATIONS OF ITCHING		YOU HAD ATTACKS OF SHORTNESS OF		
		ON YOUR SKIN	0	BREATH WHEN WALKING UP STAIRS OR		
	JJ.	Wounds that are slow to healO	0	RUNNING OR WALKING QUICKLY ON FLAT		
	KK.	SWELLING OF BOTH FEET		GROUND?	.0	.Ο
		OR BOTH ANKLES	0	T. HAS THERE BEEN AN OCCASION WHEN		_
				YOU HAD TIGHTNESS OF THE CHEST WHEN		
15	Tn.	the past 6 months (Places chases		WALKING UP STAIRS OR RUNNING OR		
13.		the past 6 months (Please choose		WALKING QUICKLY ON FLAT GROUND?	.0	.0
	"Ye	es" or "No" for each question.)				-
		<u>Yes</u>	No 16.	In the past 6 months, have you exp	erienc	ed
		Have you had problems with		extreme fatigue almost every day fo		
	I	FEELING TIRED?	0		JI I 111	IOIILII
	B . 1	HAVE YOU NEEDED TO REST MORE?O	0	or longer?		
	C. 1	HAVE YOU BEEN FEELING UNUSUALLY				
		TAVE 100 BEEN LEEDING CHOOCHEEL		A. \bigcirc No \rightarrow go to instructions before Qu	ESTION	17
		SLEEPY OR DROWSY?	0	A. ○ No → GO TO INSTRUCTIONS BEFORE QU ○ YES	<i>IESTION</i>	17
	D. 1	SLEEPY OR DROWSY?O HAVE YOU HAD PROBLEMS STARTING				
	D. 1	SLEEPY OR DROWSY?		O YES	RST BEC	GIN,
	D. 1	SLEEPY OR DROWSY?O HAVE YOU HAD PROBLEMS STARTING	0	 YES In what month and year did this field the past 6 	RST BEC	GIN,
	D. 1 E. 7	SLEEPY OR DROWSY?O HAVE YOU HAD PROBLEMS STARTING THINGS?O	0	\bigcirc Yes $ ightharpoonup$ In what month and year did this fi	RST BEC	GIN,
	D. 1 E. 7 F. 1	SLEEPY OR DROWSY?	0	YES IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year	RST BEC	GIN,
	D. 1 E. 7 F. 1	SLEEPY OR DROWSY?	0	 YES In what month and year did this field the past 6 	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year 00 00 00 00 00 00 00 00 00 00 00 00 0	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year 00 00 00 00 00 00 00 00 00 00 00 00 0	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year 00 0 010 00 010 020 020 030 040 040	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1	SLEEPY OR DROWSY? O HAVE YOU HAD PROBLEMS STARTING THINGS? O WERE YOU LACKING IN ENERGY? O HAVE YOU HAD LESS STRENGTH O HAVE YOU BEEN FEELING WEAK? O HAVE YOU HAD PROBLEMS THINKING CLEARLY? O HAVE YOU BEEN MAKING SLIPS OF THE	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year 00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B. Month Year 00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B.	RST BEC	GIN,
	D. 1 E. 7 F. 1 G. 1 H. 1 J. 1	SLEEPY OR DROWSY? O HAVE YOU HAD PROBLEMS STARTING THINGS? O WERE YOU LACKING IN ENERGY? O HAVE YOU HAD LESS STRENGTH N YOUR MUSCLES? O HAVE YOU BEEN FEELING WEAK? O HAVE YOU HAD PROBLEMS THINKING CLEARLY? O HAVE YOU BEEN MAKING SLIPS OF THE FONGUE WHEN SPEAKING?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B.	RST BEC	GIN,
	D. 1 E. 3 F. 1 G. 1 H. 1 J. 1 K. 1	SLEEPY OR DROWSY? O HAVE YOU HAD PROBLEMS STARTING THINGS? O WERE YOU LACKING IN ENERGY? O HAVE YOU HAD LESS STRENGTH IN YOUR MUSCLES? O HAVE YOU BEEN FEELING WEAK? O HAVE YOU HAD PROBLEMS THINKING CLEARLY? O HAVE YOU BEEN MAKING SLIPS OF THE TONGUE WHEN SPEAKING? O HAVE YOU HAD PROBLEMS WITH YOUR MEMORY? O HAVE YOU HAD PROBLEMS WITH	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B.	RST BEC	GIN,
	D. 1	SLEEPY OR DROWSY?	0	Yes In what month and year did this fireven if it began prior to the past 6 B.	RST BEG	gin, is?
	D. 1	SLEEPY OR DROWSY?	0	Yes IN WHAT MONTH AND YEAR DID THIS FI EVEN IF IT BEGAN PRIOR TO THE PAST 6 B.	RST BEG	gin, is?
	D. 1	SLEEPY OR DROWSY?	0	Yes In what month and year did this fireven if it began prior to the past 6 B.	RST BEG	gin, is?
	D. 1 E. 7 F. 1 G. 1 H. 1 J. 1 K. 1	SLEEPY OR DROWSY?	0	Yes In what month and year did this fireven if it began prior to the past 6 B.	RST BEG	gin, is?
	D. 1 E. 7 F. 1 G. 1 H. 1 J. 1 K. 1 L. 1	SLEEPY OR DROWSY?	0	Yes In what month and year did this fireven if it began prior to the past 6 B.	RST BEG	gin, is?

C. Did this fatigue begin with Don't Yes No know	We would now like to know if some odors or substances bother you.
1. A COLD OR FLU-LIKE ILLNESS?	17. In the past 6 months, has routine or normal exposure to substances like gasoline, hair spray, paint, household cleaners, perfume, or soap caused you to feel physically ill? A. ○ No → GO TO QUESTION 18 ○ YES □ IN WHAT MONTH AND YEAR DID THIS FIRST BEGIN, EVEN IF IT BEGAN PRIOR TO THE PAST 6 MONTHS? B. Month Year □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □
① ZERO ⑥ SIX	
① One ② Seven	
② Two ⑧ Eight	
3 THREE 9 NINE	
① FOUR	
© FIVE E. During the worst part of your fatigue, what percent of your usual daily activity were you able to maintain?	18. In the past 6 months, has exposure to the following substances caused you to be physically ill or to have difficulty thinking or functioning? (Please choose "Yes" or "No" for each substance.)
O Less than 25%	Yes No
○ 25 UP TO 50%○ 50 UP TO 75%○ 75% OR MORE	A. SMOG OR AIR POLLUTION
F. Did you see a doctor specifically for your fatigue?YESNO	D. COPIERS OR LASER PRINTERS O E. NEWSPAPERS, MAGAZINES, OR OTHER NEWSPRINT O F. PESTICIDES, HERBICIDES, INSECTICIDES, OR FERTILIZERS O G. NEW OFFICE BUILDINGS OR HOMES
G. Have you fully recovered from your fatigue?	(E.G., SEALED WINDOWS)
 ○ No → GO TO INSTRUCTIONS BEFORE QUESTION 19 ○ Don't know → GO TO INSTRUCTIONS BEFORE QUESTION 19 ○ YES → IN WHAT MONTH AND YEAR DID YOU RECOVER? 	H. CARPETING OR DRAPES
H. Month Year 00 00 00 00 00 00 00 00 00 00 00 00 00	19. In general, did you have reactions to any of these substances where you felt physically ill or had difficulty thinking or functioning before August 1990? O YES, HAD THIS TYPE OF REACTION BEFORE AUGUST 1990 No, ONLY HAD THIS TYPE OF REACTION SINCE AUGUST 1990 NEVER HAD THIS TYPE OF REACTION

	next few questions ask your views about your lth, now and during the past 4 weeks.	Not My health limits me <u>A lot</u> <u>A little</u> <u>at all</u>
20.	In general, would you say your health is (Please choose the best answer.) ① EXCELLENT ② VERY GOOD ③ GOOD ④ FAIR ③ POOR	E. CLIMBING ONE FLIGHT OF STAIRS. ① ② ③ F. BENDING, KNEELING, OR STOOPING. ① ② ③ G. WALKING MORE THAN A MILE. ① ② ③ H. WALKING SEVERAL BLOCKS. ① ② ③
21.	Compared to 1 year ago, how would you rate your health in general now? Would you say it is (Please choose the best answer.) ① Much better now than 1 year ago ② Somewhat better now ③ About the same ④ Somewhat worse now	H. Walking several blocks. ① ② ③ I. Walking one block. ① ② ③ J. Bathing or dressing yourself. ① ② ③ 24. During the past 4 weeks, have you had to cut down on the amount of time you spent on work or other activities as a result of your physical health?
	Much worse now than 1 year ago Now think about the year before the Gulf War began. That would be from August 1989 to July 1990. Would you say your general health at that time was (Please choose the best answer.) ① Excellent ② Very good ③ Good ④ Fair ③ Poor The following items are about activities you might do during a typical day. Does your health now limit you a lot, limit you a little, or	① YES ② NO 25. During the past 4 weeks, have you accomplished less than you would like, as a result of your physical health? ① YES ② NO 26. During the past 4 weeks, were you limited in the kind of work or other regular daily activities you do, as a result of your physical health? ① YES
	not limit you at all in doing these activities? Not My health limits me A lot A little at all A. Vigorous activities, Such as running, Lifting heavy objects, Participating in Strenuous sports. ① ② ③ B. Moderate activities, Such as moving a table, Pushing a vacuum Cleaner, bowling, OR Playing Golf. ① ② ③ C. Lifting or carrying GROCERIES. ① ② ③ D. Climbing several Flights of stairs. ① ② ③	 ② No 27. During the past 4 weeks, have you had difficulty performing the work or other regular daily activities you do as a result of your physical health, for example, it took extra effort? ① YES ② No 28. During the past 4 weeks, have you cut down the amount of time you spent on work or other regular daily activities as a result of any emotional problems, such as feeling depressed or anxious? ① YES ② No

 29. During the past 4 weeks, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious? ① YES ② NO 30. During the past 4 weeks, did you not do work or other regular daily activities as carefully as usual, as a result of any emotional problems, such as feeling depressed or anxious? ① YES ② NO 31. During the past 4 weeks, to what extent has your physical health, or emotional problems, interfered with your normal social activities with family, friends, neighbors, or groups? ① NOT AT ALL ② A LITTLE BIT ③ MODERATELY ④ QUITE A BIT ⑤ EXTREMELY 34. The next group of questions are about how you feel 	both work outside t ① Not at all ② A little bit ③ Moderately ④ Quite a bit ③ Extremely	veeks, how much did pa normal work including the home and housewor					in ; ·k?		
4 weeks. For each question, please give the one an feeling.	swer that comes closest to th	ie wa	Tin	ne di	ve be iring wee	the			
How much time during the rest 4 weeks	·	АLL ОF ТНЕ ТІМЕ	Моѕт оғ тне тіме	A GOOD BIT OF THE TIME	SOME OF THE TIME	А ситте ог тне тіме	NONE OF THE TIME		
How much time during the past 4 weeks		(0)	②	3	(4)	<u>'</u>	6		
A. DID YOU FEEL FULL OF PEP? B. HAVE YOU BEEN A VERY NERVOUS PERSON?		0	② ②	3	• •	<u> </u>	.		
C. HAVE YOU FELT SO DOWN IN THE DUMPS THAT NOTHING COU	I D CHEER VOILUP?	(i)	② ②	3	(A)	<u> </u>	6		
D. HAVE YOU FELT CALM AND PEACEFUL?		0	<u> </u>	3	(<u> </u>	6		
E. DID YOU HAVE A LOT ENERGY?		① ①	 	3	4)	<u> </u>	······································		
F. HAVE YOU FELT DOWNHEARTED AND BLUE?		0	② : ②	3	(4)	<u> </u>	6		
G. Did you feel worn out?	tioning of the College Base of the	(I)	② ②	③	(4)	(S)	(6)		
H. HAVE YOU BEEN A HAPPY PERSON?		ı	_	_	_	_	;		
		(1) (1)	2	3	4	(3)	6		

- 35. During the <u>past 4 weeks</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
 - ① ALL OF THE TIME
 - ② Most of the time
 - ③ Some of the time
 - A LITTLE OF THE TIME
 - ⑤ None of the time.

The next four questions are statements about health. Please tell us how true or false each of these statements is for you.

- 36. I seem to get sick a little easier than other people.
 - ① DEFINITELY TRUE
 - ② MOSTLY TRUE
 - 3 Don't know
 - Mostly false
 - **⑤** DEFINITELY FALSE
- 37. I am as healthy as anybody I know.
 - ① DEFINITELY TRUE
 - ② MOSTLY TRUE
 - 3 Don't know
 - Mostly false
 - ⑤ DEFINITELY FALSE
- 38. I expect my health to get worse.
 - ① DEFINITELY TRUE
 - ② Mostly True
 - 3 Don't know
 - Mostly false
 - 3 DEFINITELY FALSE
- 39. My health is excellent.
 - ① DEFINITELY TRUE
 - ② Mostly true
 - ① Don't know④ Mostly false
 - 3 DEFINITELY FALSE

- These questions are about medical care you may have needed in the <u>past 6 months</u>.
- 40. During the past 6 months, how many times did you go to a private outpatient facility (for example, a private clinic or a private physician's office) to obtain medical care for a physical health problem (for example, illness or injury)? Do not include routine health care such as checkups.
 - O 0 TIMES
 - O 1 TIME
 - O 2 or 3 times
 - O More than 3 times
- 41. During the <u>past 6 months</u>, how many times did you visit a hospital emergency room for a physical health problem (for example, illness or injury)?
 - O 0 TIMES
 - O 1 TIME
 - O 2 or 3 times
 - O More than 3 times
- 42. During the <u>past 6 months</u>, how many different times were you an inpatient for a physical health problem; that is, you had an overnight stay in a hospital?
 - O 0 TIMES
 - O 1 TIME
 - O 2 or 3 times
 - O More than 3 times

Below is a list of problems people sometimes have. Please read each one carefully and blacken the circle that best describes how much that problem has distressed or bothered you during the past 4 weeks.

43. Du	aring the past 4 weeks, how much were you bothered by:	Not at <u>all</u>	A <u>little</u>	Quite <u>a bit</u>	Extremely
A.	HEADACHES	①	2	3	4
В.	Nervousness or shakiness inside	①	2	3	4
C.	FAINTNESS OR DIZZINESS	0	2	3	4
D.	Loss of sexual interest or pleasure	①	3	3	(4)
E.	FEELING LOW IN ENERGY OR SLOWED DOWN	①	②	3	4
F.	THOUGHTS OF ENDING YOUR LIFE	①	②	3	(
G.	Trembling	0	@	3	4
H.	POOR APPETITE	①	@	3	4
I.	CRYING EASILY	①	②	3	4
J.	A FEELING OF BEING TRAPPED OR CAUGHT	(2	3	•
K.	FEELING SUDDENLY SCARED FOR NO REASON	①	②	3	4
L.	BLAMING YOURSELF FOR THINGS	0	②	0	•
M.	FEELING LONELY	①	2	3	④
N.	FEELING BLUE	①	3	3	④
O.	Worrying or stewing about things	①	2	3	4
P.	FEELING NO INTEREST IN THINGS	0	0	0	•
Q.	FEELING FEARFUL	①	2	3	④
R.	YOUR HEART POUNDING OR RACING	0	0	0	a
S.	DIFFICULTY IN FALLING ASLEEP OR STAYING ASLEEP	①	2	3	4
Т.	FEELING HOPELESS ABOUT THE FUTURE	0	@	3	4
	FEELING TENSE OR KEYED UP	①	2	3	④
V.	SPELLS OF TERROR OR PANIC	0	0	3	④
W.	FEELING RESTLESS, LIKE YOU CAN'T KEEP STILL	0	@	3	4
X .	FEELING EVERYTHING IS AN EFFORT	0	0	9	@
Y.	FEELINGS OF WORTHLESSNESS	0	2	3	4

This next set of questions asks about potentially upsetting experiences that happen to many people at some point in their lives. We would like to know if you had any of these experiences before you entered the military. Please record in Column 1 whether or not you had the experience before age 16. Record in Column 2 whether or not you had the experience between the time you turned 16 years of age and the time you first entered the Active Military, Reserves, or National Guard. As with all information you provide on this survey, your answers to these questions will be kept confidential.

questions will be kept confidential.	COLI	UMN 1	COLU	JMN 2
	bei 16 y	pened fore rears age?	bety age and ente	oened ween e 16 time ered tary?
	Yes	No	YES	No
44. A loved one was deliberately killed, murdered during a crime, or killed by a drunk driver. By "loved one" we mean either an immediate family member (e.g., parent, sibling) or an intimate partner (e.g., spouse, live-in partner).	0	0	0	0
45. You were in an accident or fire in which your life or a loved one's life was <u>endangered</u> . Include incidents in which you or a loved one were <u>seriously</u> injured or a loved one died.		0	0	0
46. You were in a natural disaster, such as an earthquake, tornado, or hurricane, in which your life or a loved one's life was endangered. Include incidents in which you or a loved one were seriously injured or a loved one died.	0	0	0	.0
47. Someone attacked or threatened you with a gun, knife, or some other <u>weapon</u> regardless of whether you ever reported it or not	0	0	0	
48. Someone physically assaulted you with enough force that they did or could have <u>seriously injured you</u> . Examples would include someone beating you with their fists, choking you, throwing you against a wall, or intentionally burning you.	0	0	0	0
49. Someone made you have oral, anal, or vaginal intercourse against your will by using <u>physical force</u> or by <u>threatening</u> to harm you or someone close to you.	0	0	0	0
The next three questions ask only about experiences occurring <u>before</u> <u>you were age 16</u> .				
50. Someone 5 or more years older than you had oral, anal, or vaginal intercourse with you regardless of whether or not they used physical force or threatened you.	0	0.		
51. Someone 5 or more years older than you had sexual contact with you that did not involve oral, anal, or vaginal intercourse	0	0		
52. A <u>parent or other caretaker</u> kicked, hit, or otherwise physically assaulted or punished you so that you suffered some degree of injury, including bruises, cuts, or other marks.	0	0		

The next set of questions asks about experiences you may have had while serving in the Military. Please record in Column 1 how frequently you had the experience during the time period from the date you first entered the Active Military, Reserves, or National Guard until August 1990. By "the date you first entered," we mean your earliest date of entry to military service. (For example, if you entered the Army in June 1970, then entered the Reserves in September 1980, you would answer regarding the time period from June 1970 until August 1990.)

Record in Column 2 how frequently you had the experience from the <u>time of your first deployment</u> through July 1991. Please remember that "the time of your first deployment" refers to the first time that you were deployed to the Persian Gulf during the time period from August 1990 through July 1991.

	COLUMN 1				COLUMN 2					
	Fı	Mili	itary	ente unti 1990	l ,	From time of findeployment through July 19				
NUMBER OF TIMES:	0/Never	1-2	3–12	13–50	51 or More	0/Never	1-2	3–12	13–50	51 OR MORE
53. How often did you view a continual stream of casualties?	0	0	0		0	0		3	0	
54. How often did you view casualties (Americans, enemy troops, other military personnel or civilians) who were severely wounded, disfigured or mutilated?	0	0	0	0	0	0	0	0	0	0
55. How many times were you involved in the post-mortem preparation and/or evacuation of bodies?	0	0		0			0			
56. How often were you under (enemy) fire?		0		0		0	0		0	
57. How many times did you see people critically injured or killed because of leadership errors, personnel shortages, or equipment malfunction?			5	0		0		:		
58. How many times did you have to decide who would receive life saving care?		0	0	0		0		0	0	0
59. How often were you in actual danger of being injured or killed (i.e., received incoming rockets, mortars, or small arms fire; pinned down or overrun)?	0	0		0	0	, 0	0	0 :	0	0
60. How many times did you go on patrol or have other very dangerous duty (e.g., convoys, hazardous transport, guard duty with enemy in the vicinity)?		0		0				O .	0. 1	
61. How many times were you placed on alert for any form of enemy attack (e.g., rocket, mortar, chemical, biological, etc.)?	0	0	0	0	0	0 2	0		0 (

	COLUMN 1				COLUMN 2					
Please note that questions 62.60 and and 1	From time entered military until August 1990					From time of fir deployment through July 199				
Please note that questions 62-69 are rated on a scale from "Never" to "4 or more" times (rather than from "Never" to "51 or more" times).	0/Never				OR MORE	0/Never				OR MORE
NUMBER OF TIMES:	√O	1	2	3	4 0	NO	-	2	m	4 01
62. How often did you sit with someone dying from military-related causes?	0	0	0	0	0	0	0	0	0	0
63. How many times did you make critical or life- threatening errors in your work because of excessive fatigue or work load (i.e., as compared to the average level of fatigue or work load in the military)?	0	0	0	0	0	0	0	0	0	0
64. How often were you responsible for making the decision to allow someone to die?	0	0	0	0	0	0	0	0	Ó	0
65. How often did you provide care or services to enemy personnel that was of lesser quality than you were actually able to give?	0	O	0	0	0	0	O	0	0	0
66. How many times did you lose communications or become cut-off from contact with your own unit or other units?	0	0	0	0	0	0	O	0	O	0
67. How many times was a woman or man you knew, or were close to, killed, wounded, or missing in action? (By how many times we mean how many people this happened to.)	0	0	0 3	0	0	0	0	ъ. О	O	0
The next two questions ask about unwanted sexual experiences occurring in the Military.										
68. How often did anyone make you have oral, anal, or vaginal intercourse against your will by using physical force or threatening to harm you or someone close to you?			0	0	0		0	0		0
69. How often did you experience sexual harassment that did not involve oral, anal, or vaginal intercourse? Examples would include unwanted sexual touching, grabbing, or brushing against you.	0	0	0	0	0	0		0	0	0
	-								77	

These next questions ask about substances that you may have had direct contact with or were exposed to during the time of your first deployment. We would like to know the total number of days you think you were exposed to these substances. Please consider any part of a day as 1 day.

	0 days	1-5 days	6-30 days	31 or more
70. How many days were you exposed to:				
A. Smoke from oil well fires	0	0	0	0
B. Exhaust from heaters or generators (e.g., kerosene heaters)	0	0	0	0
C. Diesel and/or other petrochemicals, including paint or solvents (exposure to fumes or contact with skin)	0	0	0	0
D. CARC (CHEMICAL AGENT RESISTANT COMPOUND) PAINT	0	0	0	0
E. BURNING TRASH OR BURNING FECES	0	0	0	0
F. Depleted uranium	0	0	0	0
G. Microwaves	0	0	0	0
H. Pesticides like cream, sprays, or flea collars or pesticides on clothing or bedding	0	0	0	0
I. Nerve gas	0	0	0	0
J. MUSTARD GAS OR OTHER BLISTERING AGENTS	0	0	0	0
K. FOOD CONTAMINATED WITH SMOKE, OIL, OR OTHER CHEMICALS	0	0	0	0
L. Local food other than food provided by the Armed Forces	0	0	0	0
M.Dead animals	0	0	0	0
N. BATHING OR DRINKING WATER CONTAMINATED BY SMOKE, OIL, OR OTHER CHEMICALS	0		0	C

How many days were you exposed to:	0 days	1-5 DAYS	6-30 days	31 or more
O. WATER FROM A LOCAL POND, RIVER OR PERSIAN GULF WATER (SWIMMING OR BATHING)	0	0	0	0

These next questions ask about other experiences you may have had up to 1 year before your first deployment, as well as during your first deployment to the Persian Gulf. Specifically, we would like to know if you had any of these experiences at any time during the period from August 1989 through July 1991.

71.	From August 1989 through July 1991, how many preventive vaccines did you receive orally (by mouth) or by injection (by shots)? (Please choose the best answer.)
	O 0/None
	O 1-5
	○ 6-10
	○ 11 OP MODE

- 72. From August 1989 through July 1991, did you receive a vaccine for anthrax immunization?
 - O YES
 - O No
 - O Don't know
- 73. From August 1989 through July 1991, did you receive a vaccine for botulism immunization?
 - O Yes
 - O No
 - O Don't know
- 74. From August 1989 through July 1991, how many pyridostigmine bromide tablets did you take in total? (Pyroidostigmine bromide tablets are little white pills, sometimes called NAPPS, that come in a foil pack and are used to protect against nerve agents.)
 - O 0/None
 - 0 1-10
 - O 11-30
 - O 31 OR MORE

The following is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then blacken a circle to the right to indicate how much you have been bothered by that problem in the past 6 months. (Please choose the best answer for each question.)

	Time during past 6 mont				
In the past 6 months how much have you been bothered by:	Not at all	LITTLE BIT	Moderately	Опте а віт	EXTREMELY
75. Repeated, disturbing <u>memories, thoughts, or images</u> of a stressful experience from the past?	<u>Z</u>		·		(E)
76. Repeated, disturbing <u>dreams</u> of a stressful experience from the past?	0	2		4	(S)
77. Suddenly <u>acting or feeling</u> as if a stressful experience from the past <u>were happening again</u> (as if you were reliving it)?	0	②		(:
78. Feeling <u>very upset</u> when <u>something reminded you</u> of a stressful experience from the past?	0	2	3	④	⑤
79. Having <u>physical reactions</u> (e.g., heart pounding, trouble breathing, sweating) when <u>something reminded</u> you of a stressful experience from the past?	0	2	3	•	S
80. Avoiding thinking about or talking about a stressful experience from the past or avoiding having feelings related to it?	Θ	2	3	4	S
81. Avoiding <u>activities or situations</u> because <u>they reminded you</u> of a stressful experience from the past?	0	2	3	④	3
82. Trouble <u>remembering important parts</u> of a stressful experience from the past?	0	②	3	•	3
83. Loss of interest in activities that you used to enjoy?	. ①	2	3	•	3
84. Feeling distant or cut off from other people?	0	2	3	4	③
85. Feeling emotionally numb or being unable to have loving feelings for those					
close to you?		0	3	- 17 T-9	(5)
86. Feeling as if your <u>future</u> somehow will be <u>cut short</u> ?					
87. Trouble <u>falling or staying asleep</u> ?				200	
88. Feeling <u>irritable</u> or having <u>angry outbursts</u> ?		100			- 1
89. Having difficulty concentrating?		4.3			- 1
90. Being "superalert" or watchful or on guard?		Sec. 15.	,	10.00	
91. Feeling jumpy or easily startled	① :	2	3	④	③

Now, we would like to know about any pregnancies you have had or fathered since the time of your first deployment to the Persian Gulf Theater. Please think about pregnancies from all relationships you may have had. Include live births, stillbirths, tubal or ectopic pregnancies, miscarriages, as well as induced abortions.

- 92. Since the time of your first deployment, how many of the pregnancies you had or fathered resulted in induced abortions?
 - O HAVE NOT HAD OR FATHERED A PREGNANCY SINCE THAT TIME
 - No pregnancies have had or fathered since that time have resulted in this
 - O 1 PREGNANCY
 - O 2 PREGNANCIES
 - O 3 PREGNANCIES
 - O 4 OR MORE PREGNANCIES
- 93. Since the time of your first deployment, how many of the pregnancies you had or fathered resulted in stillbirths, tubal or ectopic pregnancies, or something else like molar pregnancies?
 - O HAVE NOT HAD OR FATHERED A PREGNANCY SINCE THAT TIME
 - No pregnancies have had or fathered since that time have resulted in this
 - O 1 PREGNANCY
 - O 2 PREGNANCIES
 - O 3 PREGNANCIES
 - O 4 OR MORE PREGNANCIES
- 94. Since the time of your first deployment, have any of your children been born prematurely, that is, before 36 weeks?
 - O YES
 - O No
 - O HAVE NOT HAD OR FATHERED ANY CHILDREN SINCE THAT TIME
- 95. Since the time of your first deployment, have any of your children weighed less than 5 pounds at birth?
 - O YES
 - O No
 - O HAVE NOT HAD OR FATHERED ANY CHILDREN SINCE THAT TIME

- 96. Have any of your children born since the time of your first deployment been diagnosed with any birth defect, congenital or hereditary condition, or developmental problem, such as slow or abnormal physical, intellectual, or mental growth?
 - O YES
 - O No
 - O HAVE NOT HAD OR FATHERED ANY CHILDREN SINCE THAT TIME
- 97. How many children under age 17 <u>currently</u> live with you? Please include in your count adopted, step, and foster children who live with you, as well as your own biological children.
 - O No children under 17 live with me
 - O 1 CHILD
 - O 2 CHILDREN
 - O 3 CHILDREN
 - O 4 CHILDREN
 - O 5 OR MORE CHILDREN

The next question asks about tobacco use.

- 98. Think about the <u>past 30 days</u>. How many cigarettes did you <u>usually</u> smoke on a <u>TYPICAL day</u>?
 - O ABOUT 3 OR MORE PACKS A DAY (MORE THAN 55 CIGARETTES)
 - O ABOUT 2-1/2 PACKS A DAY (46-55 CIGARETTES)
 - O ABOUT 2 PACKS A DAY (36-45 CIGARETTES)
 - O ABOUT 1-1/2 PACKS A DAY (26-35 CIGARETTES)
 - O ABOUT 1 PACK A DAY (16-25 CIGARETTES)
 - O ABOUT 1/2 PACK A DAY (6-15 CIGARETTES)
 - O 1-5 CIGARETTES A DAY
 - O Less than 1 cigarette a day, on the average
 - O DID NOT SMOKE ANY CIGARETTES IN THE PAST 30 DAYS
 - O Never smoked cigarettes in my life

Next, we would like to know about your use of alcohol. By "alcohol," we mean beer, wine, wine coolers, and hard liquor, such as bourbon, gin, vodka, and so on. Please answer ALL of the following alcohol use questions even if you don't drink or you're not a regular drinker.

- 99. During the <u>past 30 days</u>, on how many days did you drink one or more drinks of alcoholic beverages? Count as a drink a can or bottle of beer; a wine cooler or a glass of wine, champagne, or sherry; or a shot of liquor or a mixed drink or cocktail.
 - O 28-30 days (about every day)
 - O 20-27 days (5-6 days a week, average)
 - O 11-19 DAYS (3-4 DAYS A WEEK, AVERAGE
 - O 4-10 DAYS (1-2 DAYS A WEEK, AVERAGE)
 - O 2-3 days in the past 30 days
 - O ONCE IN THE PAST 30 DAYS
 - O None in the past 30 days
 - O NEVER DRANK ALCOHOLIC BEVERAGES IN MY LIFE
- 100. Think about the days when you drank in the past 30 days. How many drinks did you usually drink on a TYPICAL day? Count as a drink a can or bottle of beer; a wine cooler or a glass of wine, champagne, or sherry; or a shot of liquor or a mixed drink or cocktail.
 - O 9 DRINKS OR MORE
 - O 8 DRINKS
 - O 7 DRINKS
 - \bigcirc 6 drinks
 - O 5 DRINKS
 - \bigcirc 4 drinks
 - O 3 drinks
 - O 2 DRINKS
 - O 1 DRINK
 - \bigcirc DID NOT DRINK ALCOHOLIC BEVERAGES IN THE PAST 30 DAYS
 - O NEVER DRANK ALCOHOLIC BEVERAGES IN MY LIFE
- 101. During the <u>past 30 days</u>, on how many days did you have 5 or more drinks on the same occasion? By "occasion," we mean at the same time or within a couple of hours of each other.
 - O 28-30 DAYS (ABOUT EVERY DAY)
 - O 20-27 DAYS (5-6 DAYS A WEEK, AVERAGE)
 - O 11-19 DAYS (3-4 DAYS A WEEK, AVERAGE)
 - O 4-10 DAYS (1-2 DAYS A WEEK, AVERAGE)
 - O 2-3 days in the past 30 days

- O ONCE IN THE PAST 30 DAYS
- O Drank during the past 30 days, but never had 5 or more drinks on the same occasion
- O DID NOT DRINK ALCOHOLIC BEVERAGES IN THE PAST 30 DAYS
- O NEVER DRANK ALCOHOLIC BEVERAGES IN MY LIFE
- 102. In your entire life, has a doctor <u>ever</u> suggested that you stop drinking because of a problem with your health related to your drinking?
 - No → GO TO QUESTION 103
 - O YES
 - HAVE YOU HAD ANY DRINKS
 OF ALCOHOL SINCE THAT TIME?
 - O YES
 - O No

We are now going to ask about experiences you may have had using alcohol during the past 6 months.

- 103. Were you drinking, high from alcohol, or hung over while you were working, going to school, or taking care of other responsibilities, more than once?
 - O YES
 - O No
- 104. Were you missing or late for work, school, or other responsibilities because you were drinking or hung over, more than once?
 - O YES
 - O No
- 105. Did you have a problem getting along with other people while you were drinking more than once?
 - O YES
 - O No

The next few questions ask about your physical and mental health <u>during the past 6 months</u>, as <u>well as during your entire life</u>.

- 106. During the <u>past 6 months</u>, have you had three or more <u>physical problems</u> that have not been adequately understood or explained by your doctor?
 - O YES
 - O No

107. In your entire life, have you ever seen a physician or other professional like a psychologist or social worker, for a psychiatric disorder, illness, or emotional or mental health problem, such as anxiety, depression, alcohol, or drug abuse? O YES O No	112. In the past 30 days, how many days were you able to work and carry out your normal activities, but had to cut down on what you did or did not get as much done as usual because of emotional difficulties or physical health problems? O DAYS O 1-2 DAYS
108. During the past 6 months, how many times did you visit a mental health professional for a psychiatric disorder, illness, or emotional or mental health problem, such as anxiety, depression, or alcohol or drug abuse? O 1 time O 2 or 3 times O more than 3 times O Have not visited a mental health professional in the past 6 months O Have never visited a mental health professional	 ○ 3-5 DAYS ○ 6-7 DAYS ○ 8-10 DAYS ○ 11 OR MORE DAYS 113. Have you been unemployed for 3 months or longer since July 1991? ○ YES ○ No 114. Was this unemployment due to emotional difficulties or physical health problems?
109. In your entire life, have you ever been hospitalized for an emotional or psychiatric problem? O YES O No	 ○ YES ○ No ○ WAS NOT UNEMPLOYED FOR 3 MONTHS OR LONGER 115. Which of the following best describes your current work situation? (Please choose the
These next questions are about your work and your life in general. 110. In the past 30 days, how many days have you missed from your job for any reason? (Please do not include scheduled vacation time.)	best answer.) Working for pay (INCLUDES ACTIVE-DUTY MILITARY) Have a job, but not working (BECAUSE OF MATERNITY LEAVE, BAD WEATHER, STRIKE, SEASONAL WORK, TEMPORARY LAYOFF, ETC.) UNEMPLOYED OR PERMANENTLY LAID OFF
 ○ Have not worked for pay in the past 30 days ○ 0 days ○ 1-2 days ○ 3-5 days ○ 6-7 days ○ 8-10 days ○ 11 or more days 	AND LOOKING FOR WORK UNEMPLOYED OR PERMANENTLY LAID OFF AND NOT LOOKING FOR WORK KEEPING HOUSE FULL-TIME In school or training program RETIRED DISABLED
111. In the past 30 days, how many days have you missed a day from work, or were not able to carry out your usual activities because of emotional difficulties or physical health problems? O DAYS O 1-2 DAYS O 3-5 DAYS O 6-7 DAYS O 8-10 DAYS O 11 OR MORE DAYS	

116.	In the <u>past 3 months</u> , how many hours per week did you usually work for pay? (Please choose the best answer.)	120. In your <u>entire life</u> , how many years have you served in the Guard or Reserves? Do not include Active-Duty years. (Please choose the
117.	O HAVE NOT WORKED FOR PAY DURING PAST 3 MONTHS O 1-9 HOURS PER WEEK O 10-14 HOURS PER WEEK O 15-19 HOURS PER WEEK O 20-24 HOURS PER WEEK O 25-29 HOURS PER WEEK O 30-34 HOURS PER WEEK O 35-40 HOURS PER WEEK O MORE THAN 40 HOURS PER WEEK	best answer.) Have never served in the guard or reserves Less than 6 months At least 6 months, but less than 1 year At least 1 year, but less than 2 years At least 2 years, but less than 3 years At least 3 years, but less than 4 years At least 4 years, but less than 5 years At least 5 years, but less than 10 years At least 10 years, but less than 20 years O at least 10 years, but less than 20 years
	disability that currently keeps you from	
	working?	121. What is your current marital situation?
	O YES O No	(Please choose the best answer.) O Not married, but living as married
118.	Currently, in which component of the Military do you serve? (Please choose the best answer.) O I do not currently serve in the Military O Active Army (USA) O Army National Guard (ARNG)	O Married, But Living as married O Married O Separated and not living as married O Divorced and not living as married O Widowed and not living as married O Single, never married, and not living as married 122. What is the month, day, and year of your birth? Please be sure to blacken the circles
	O Army Reserve (USAR) O Active Navy (USN)	under the boxes in which you write in the date.
440	O NAVAL RESERVE (USNR) O ACTIVE AIR FORCE (USAF) O AIR NATIONAL GUARD (ANG) O AIR FORCE RESERVE (USAFR) O ACTIVE MARINE CORP (USMC) O MARINE CORPS RESERVE (USMCR)	Month Day Year 00 00 00 00 00 00 00 00 00 00 00 00 00
119.	In your entire life, how many years have	
	you served on Active Duty? Do not include Reserve/Guard years. (Please choose the best answer.)	
	O HAVE NOT SERVED ON ACTIVE DUTY	123 Are you male or female?

- O MALE
- O FEMALE

O Less than 6 months

O 20 or more years

O AT LEAST 6 MONTHS, BUT LESS THAN 1 YEAR

O At least 1 year, but less than 2 years O AT LEAST 2 YEARS, BUT LESS THAN 3 YEARS O At least 3 years, but less than 4 years O AT LEAST 4 YEARS, BUT LESS THAN 5 YEARS O AT LEAST 5 YEARS, BUT LESS THAN 10 YEARS O AT LEAST 10 YEARS, BUT LESS THAN 20 YEARS

12 ii The you of Spanish of Hispanic Origin	126. During the <u>past 12 months</u> , approximately
or descent? (Please choose the best answer.)	how much income before taxes and deduc-
O No (not Spanish or Hispanic)	tions was received by all family members
O YES, PUERTO RICAN	who live with you? Please include not only
O Yes, Mexican or Mexican-American or Chicano	money from wages, tips, and bonuses,
O Yes, Cuban	
O YES, CENTRAL OR SOUTH AMERICAN	but also social security, retirement income,
O YES, OTHER SPANISH OR HISPANIC ORIGIN	unemployment or disability payments, public
	assistance, etc. Also include income from
125. Which of these categories best describes you?	interest, dividends, net income from business,
O American Indian/Eskimo/Aleut	farm, or rent, and any other money income
O BLACK/AFRICAN-AMERICAN	your family received.
O Asian/Chinese/Japanese/Korean/	<u>-</u>
FILIPINO/ASIAN/INDIAN/PACIFIC ISLANDER	0 0 - \$4,999 0 \$5,000 \$0,000
O WHITE/CAUCASIAN	O \$5,000 - \$9,999
O OTHER	○ \$10,000 - \$14,999 ○ \$15,000 - \$19,999
OTHER	
126 What is your highest level of advection	○ \$20,000 - \$29,999 ○ \$30,000 - \$39,999
126. What is your <u>highest</u> level of education now?	○ \$30,000 - \$39,999 ○ \$40,000 - \$49,999
(Please choose the best answer.)	○ \$40,000 - \$49,999 ○ \$50,000 - \$74,999
O HAVE NOT YET GRADUATED FROM HIGH SCHOOL	○ \$75,000 - \$74,999 ○ \$75,000 - \$99,999
O GED or ABE certificate	○ \$73,000 - \$99,999 ○ \$100,000 - \$149,999
O High school graduate	○ \$100,000 - \$149,999 ○ \$150,000 - \$200,000
O Trade or technical school graduate	O More than \$200,000
O Some college but not a 4-year degree	C INDICE THAIR \$200,000
O 4-year college degree (BA, BS, or equivalent)	129. How many individuals, including yourself,
O Graduate or professional study but no	
GRADUATE DEGREE	are supported by the family income you
O Graduate or professional degree	reported in Question 128?
	O 1 person
127. During the <u>past 12 months</u> , approximately	O 2 PEOPLE
how much income before taxes and deduc-	O 3 PEOPLE
tions did <u>you</u> personally earn from jobs or	O 4 PEOPLE
other employment (including self-employ-	O 5 PEOPLE
ment)? Please, only include money from	O 6 PEOPLE
wages, salaries, tips, or bonuses that <u>you</u>	O 7 PEOPLE
	O 8 PEOPLE
received while working for pay. As with all	O 9 PEOPLE
information you provide on this survey, your	O 10 or more people
answer to this question is kept confidential.	
O 0 - \$4,999	
O \$5,000 - \$9,999	
O \$10,000 - \$14,999	
○ \$15,000 - \$19,999	
O \$20,000 - \$29,999	
○ \$30,000 - \$39,999	
O \$40,000 - \$49,999	·
O \$50,000 - \$74,999	
O \$75,000 - \$99,999	
O \$100,000 - \$149,999	
O \$150,000 - \$200,000	
O More than \$200, 000	

130. Because we may wish to talk further with some of you at another time, we would like to obtain your home phone number. Please enter your phone number, including area code, in the grid below, remembering to blacken the circle under each number. If you are currently living outside the United States, but expect to be living in the U.S. within the next 6 months, please enter your permanent home phone number.

A.	Area Code			Ph	one	Nun	ıber			
		_				-				
	000	-	0	0	(-	0	<u></u>	<u>@</u>) (
		-	ľΨ	\odot	\odot	-	\odot	\odot	\odot	\odot
	000	-	(3)	②	(2)	-	(3)	②	②	②
	[333]	-	[③	③	③	-	(3)	③	③	③
	444	-	④	④	④	-	(4)	④	④	④
	000	-	③	③	③	-	(3)	③	③	③
	666	-	[⑥	6	⑥	-	6	6	6	⑥
	000	-	1	7	0	-	0	①	7	0
	888	-	8	8	®	-	8	8	8	®
	999	-	9	<u> </u>	9	-	9	9	<u> </u>	9

- B. Please blacken the circle next to the description that best describes your current situation:
 - O I CURRENTLY RESIDE IN THE U.S. AND EXPECT TO BE RESIDING IN THE U.S. FOR AT LEAST THE NEXT 6 MONTHS.
 - O I CURRENTLY RESIDE IN THE U.S. BUT DO NOT EXPECT TO BE RESIDING IN THE U.S. FOR AT LEAST 6 MONTHS.
 - O I AM CURRENTLY RESIDING OUTSIDE THE U.S. BUT EXPECT TO RETURN TO THE U.S. WITHIN THE NEXT 6 MONTHS AND HAVE INCLUDED MY PERMANENT HOME PHONE NUMBER.
 - O I AM CURRENTLY RESIDING OUTSIDE THE U.S. BUT EXPECT TO RETURN TO THE U.S. WITHIN THE NEXT 6 MONTHS AND DO NOT HAVE A PERMANENT HOME PHONE NUMBER.



The next section is for women only. If you are a woman, please complete this last section. If you are a man, you may turn to the last page of the questionnaire for instructions regarding how to get more information on services available to Gulf War veterans. Thank you for completing this questionnaire.

	section asks questions about women's health s, including health care and medical conditions.
131.	During the <u>past 6 months</u> , did you have any of these conditions? Include times you have had these conditions even if you didn't seek medical care.
	A. \bigcirc Have had a hysterectomy or am postmenopausal \rightarrow Go to question 132
	In the past 6 months, I have had: Yes No
	B. Premenstrual symptoms or pain (PMS, premenstrual cramps)
132.	During the past 6 months, did you have any of the following conditions? Include times you have had these conditions even if you didn't seek medical care.
	In the past 6 months, I have had: Yes No A. DISCHARGE FROM BREAST

E. ABDOMINAL PAIN

F. ABDOMINAL PAIN

(FROM KNOWN CYSTS)O....O

(FROM UNKNOWN CAUSE)

	A Pap smear is when a health care provider
	inserts a swab into your vagina to scrape
	cells from the cervix. Have you ever had
	a Pap smear where the result was NOT
	normal?

- O YES
- O No
- O NEVER HAD A PAP SMEAR
- O Don't know

134. Since the time of your first deployment, have you or a health care provider ever found a lump or other abnormality in your breast?

O YES

O No

Sometimes when people have participated in a study like the Gulf War Veterans Health Survey, they are interested in following up on some of the issues that they have been asked about in the study with someone who is professionally trained to deal with these kinds of issues. There are many resources available to military personnel who served during the Persian Gulf War. Below, we have provided two toll-free numbers and two Internet addresses for resources that provide a wide variety of information about Persian Gulf War veteran programs and services. Information available through these sources ranges from providing answers to veterans' frequently asked questions, to information on the treatment services (including mental health and physical health services) that are available in your area. These numbers and Internet addresses are also provided in the introductory letter that came with this questionnaire.

Toll-Free Numbers

For current active-duty military personnel—Department of Defense Persian Gulf Veterans Hotline:

1-800-796-9699

For other Gulf War veterans—VA Persian Gulf Information Helpline:

1-800-PGW-VETS (or 1-800-749-8387)

Internet Addresses for Informational Sites on the World Wide Web

http://www.va.gov/health/environ/persgulf.htm http://www.gulflink.osd.mil/medical/#cbid

2

Thank you for completing this questionnaire.

APPENDIX B

- 1. Informational Brochure for Gulf War Veterans Health Survey
 - ♦ Cover graphic
 - Text for Gulf War veterans who are currently on active duty
 Text for Gulf War veterans who are currently civilians
- 2. Consent Form/Letter
 - ♦ For Gulf War veterans who are currently on active duty
 ♦ For Gulf War veterans who are currently civilians



WHAT IS THE GULF WAR VETERANS HEALTH SURVEY?

Duke University Medical Center and the Research Triangle Institute of North Carolina, a not for profit research organization, are conducting a research study to learn more about Gulf War Illnesses and the overall health of Gulf War veterans. You are one of 10,000 men and women being contacted about participating in the study because you served in the Persian Gulf during Operation Desert Shield/Desert Storm. This study will gather information from Gulf War veterans about their military experiences, Persian Gulf experiences, physical health, and emotional health.

WHY IS THIS STUDY IMPORTANT?

we examine a broader range of factors that Shield/Desert Storm, over 100,000 have reported health concerns to the Department of Veterans Affairs or the Department of Defense. The cause of many of these health problems are not currently known. Recent research has begun to better document, describe, and identify potential causes for these health problems, but much remains to might have affected the health of Gulf War veterans and (2) we have selected individuals Of the nearly 700,000 military personnel be learned. Our study builds upon these previous studies in two important ways: (1) for the study to represent all military personnel who served in the Gulf War. We in Operation

have chosen this approach to insure, to the best of our ability, that the information gathered will provide medical professionals, scientists, the Veterans Affairs, and military officials with a representation of the experiences and health concerns of *all* veterans that served in Operation Desert Shield/Desert Storm.

WHY IS YOUR PARTICIPATION IMPORTANT?

Because we are trying to represent the experiences of all Gulf War veterans, your participation is expecially important. Your responses will represent not only your experiences, but also the experiences of many other Gulf War Veterans who are similar to you in some way such as gender or branch of service.

WHAT DOES PARTICIPATING INVOLVE?

In about one week you will receive a questionnaire in the mail to complete along with necessary instructions. The questionnaire should take no longer than 1 hour to complete.

WHAT WILL YOU GAIN BY PARTICIPATING?

By completing the questionnaire, you will be helping us to better understand the health concerns of Gulf War Veterans. It is our

hope that findings from this study will ultimately lead to the development of better treatments and services for Gulf War veterans and will help prevent similar problems in future deployments.

WILL YOUR ANSWERS BE KEPT CONFIDENTIAL?

All information collected from you in this study will be kept strictly confidential. Your name will never be associated directly with the answers that you give. Any results that are reported from the study will refer to group information only. Only research staff conducting the study will have access to your answers. No military or VA personnel will see your answers or even know whether or not you participated in the study.

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have chosen this approach to insure, to the best of our ability, that the information gathered will provide medical professionals, scientists, the Veterans Affairs, and military officials with a representation of the experiences and health concerns of all veterans that served in Operation Desert Shield/Desert Storm.

WHY IS YOUR PARTICIPATION IMPORTANT?

Because we are trying to represent the experiences of all Gulf War veterans, your participation is expecially important. Your responses will represent not only your experiences, but also the experiences of many other Gulf War Veterans who are similar to you in some way such as gender or branch of service.

WHAT DOES PARTICIPATING INVOLVE?

In about one week you will receive a questionnaire in the mail to complete along with necessary instructions. The questionnaire should take no longer than 1 hour to complete.

WHAT WILL YOU GAIN BY PARTICIPATING?

By completing the questionnaire, you will be helping us to better understand the health concerns of Gulf War Veterans. It is our

hope that findings from this study will ultimately lead to the development of better treatments and services for Gulf War veterans and will help prevent similar problems in future deployments. Additionally, as a token of our appreciation, when you return your questionnaire, you will be entered into a drawing to win one of 10 cash prizes (ranging from \$150 to \$500 depending on how quickly you complete and return your questionnaire).

WILL YOUR ANSWERS BE KEPT CONFIDENTIAL?

All information collected from you in this study will be kept strictly confidential. Your name will never be associated directly with the answers that you give. Any results that are reported from the study will refer to group information only. Only research staff conducting the study will have access to your answers. No military or VA personnel will see your answers or even know whether or not you participated in the study.



[Insert Anticipated Date of Mailing]

Dear Gulf War Veteran:

Duke University Medical Center and the Research Triangle Institute of North Carolina, a nonprofit research organization, are conducting a research study funded by the U.S. Army to learn more about Gulf War Illnesses and health problems experienced by Gulf War veterans.

You are one of 10,000 men and women who have been contacted about participating in this study because you served in the Persian Gulf between August 1990 and July 1991. Because it is impossible for us to survey all Gulf War veterans, we have selected individuals for this research so that their responses can represent many other veterans who are similar in gender and other characteristics. You have been selected as one of those individuals and therefore your participation is very important to insure that we can accurately represent the views of all Gulf War veterans. However, your participation is completely voluntary. Your decision on whether or not to participate will in no way affect health care or other benefits that you or your family receive or are entitled to. You only need to complete the enclosed survey if you wish to be enrolled in this research study.

The survey asks questions about your military history, your Persian Gulf experiences, stressful experiences you may have had in your life, your physical health, and your emotional functioning. Some of these questions may make you feel somewhat uncomfortable or stimulate other feelings such as sadness. You may skip any questions you do not want to answer. There are no direct benefits to you from answering these questions but results from the study could help improve treatment of Gulf War veterans and prevent health problems in future conflicts. Below, we have included toll-free numbers that you can call if you would like to discuss any questions or concerns about your experiences as a Gulf War veteran.

Please complete the questionnaire in private and do not show it to anyone. Please read the instructions in the questionnaire carefully. USE ONLY A SOFT LEAD (NO. 2) PENCIL. We have included a study souvenir pencil that can be used to complete the questionnaire. We expect the questionnaire will take less than one hour to complete. In order to assure complete confidentiality you will mail your completed questionnaire directly to a civilian scoring contractor. Your name will never be associated with the responses you give. Any identifying information that would link you to your answers will be kept separate from your answers and stored in a secure location at the Research Triangle Institute. Any results that are reported from this study will refer to group data only. Only the research staff at the Research Triangle Institute, Duke University Medical Center and National Computer Systems will have access to the study data. No military personnel will see your answers or even know whether or not you participated in the study. When you have finished, seal the questionnaire in the enclosed envelope and put it into the US mail to send to National Computer Systems. No postage is required.

Some veterans who complete this survey will be contacted again and asked to participate in a telephone interview that is a second phase of the current study. The second phase telephone interview will help us get more detailed information on the health problems of Gulf War veterans and factors contributing to these. Additionally, participants in this mail survey may be asked in the future to participate in other related studies. You can decide at that time if you want to take part in the second phase telephone interview or any other related studies. Completing this mail survey does not mean that you agree to participate in the second phase telephone interview or any other related studies that may be conducted in the future.

If you have any questions about this survey, you may call Dr. Robert Bray at 1-800-334-8571, x6433 or Dr. John Fairbank at 919-687-4686, x265. If you have any questions about your rights as a research participant, you may call Dr. Steven Garfinkel at 1-800-334-8571, x6382.

Sincerely,

John A. Fairbank, Ph.D. Associate Professor of Medical Psychology, Duke University Medical Center

Robert M. Bray, Ph.D. Senior Research Psychologist, Research Triangle Institute

GULF WAR INFORMATION SOURCES

Toll-free information lines: 1-800-796-9699 (for current active duty military personnel) 1-800-749-8387 (for other Gulf War veterans)

Informational sites on the World Wide Web: http://www.va.gov/health/environ/persgulf.htm



[Insert Anticipated Date of Mailing]

Dear Gulf War Veteran:

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Please complete the questionnaire in private and do not show it to anyone. Please read the instructions in the questionnaire carefully. USE ONLY A SOFT LEAD (NO. 2) PENCIL. We have included a study souvenir pencil that can be used to complete the questionnaire. We expect the questionnaire will take less than one hour to complete. In order to assure complete confidentiality you will mail your completed questionnaire directly to a civilian scoring contractor. Your name will never be associated with the responses you give. Any identifying information that would link you to your answers will be kept separate from your answers and stored in a secure location at the Research Triangle Institute. Any results that are reported from this study will refer to group data only. Only the research staff at the Research Triangle Institute, Duke University Medical Center and National Computer Systems will have access to the study data. No military personnel will see your answers or even know whether or not you participated in the study. When you have finished, seal the questionnaire in the enclosed envelope and put it into the US mail to send to National Computer Systems. No postage is required.

Once we have received your questionnaire, as a token of our appreciation, you will be entered into a drawing to win one of 10 cash prizes. To preserve confidentiality, the identification number on your survey rather than your name will be used in this drawing. Completed questionnaires returned by [insert Month day, 2001] will be entered into the drawing for two Grand Prizes of \$500. Those returned by [insert Month day, 2001] will be entered into the drawing for four First Prizes of \$250, and those returned by [insert Month day, 2001] will be entered into the drawing for four Second Prizes of \$150. Drawings will be held within 4 weeks of the above-specified deadlines. Your chances of winning a prize (i.e., 10/10,000 or better) depend on how many veterans complete and return their questionnaires by these deadlines. If you are entered into a drawing and are not

selected, you will automatically be entered in the drawing for the next round of prizes. If you are selected in one of the drawings, you will receive notification by mail along with a check for your prize. Your responses to this survey will, however, remain confidential because no one individual will ever have access to your name, identification number, and survey responses.

Some veterans who complete this survey will be contacted again and asked to participate in a telephone interview that is a second phase of the current study. The second phase telephone interview will help us get more detailed information on the health problems of Gulf War veterans and factors contributing to these. Additionally, participants in this mail survey may be asked in the future to participate in other related studies. You can decide at that time if you want to take part in the second phase telephone interview or any other related studies. Completing this mail survey does not mean that you agree to participate in the second phase telephone interview or any other related studies that may be conducted in the future.

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John A. Fairbank, Ph.D. Associate Professor of Medical Psychology, Duke University Medical Center

Robert M. Bray, Ph.D.
Senior Research Psychologist, Research Triangle Institute

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APPENDIX C

Bibliography of Literature on Gulf War Illnesses (Draft)

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APPENDIX D

Approvals/Clearances From Military

- 1. Documentation that DAMD17-98-8662 does not require OMB review and is not subject to DoD 8910.1-M
- 2. Documentation of Human Subjects Approval from U.S. Army-Ft. Detrick.

Ebert, Lori

To:

[NSCAW] Fairbank, John

Cc:

Ebert, Lori

Subject: FW: Reply to April 12, 2000 Letter

E-mail message from Bob Cushing, DoD Clearance Officer to Dr. Robert Bray at RTI stating that DAMD17-98-1-8662 "Relationships of Stress Exposures to Health in Gulf War Veterans" does not require OMB review and approval.

----Original Message-----

From: Cushing, Bob, CIV, WHS/DIOR [mailto:CushingR@osd.pentagon.mil]

Sent: Thursday, April 13, 2000 2:23 PM

To: RMB@rti.org

Cc: Elig, Tim W.,, DMDCEAST

Subject: Reply to April 12, 2000 Letter

Importance: High

Dr. Bray,

I received the subject information regarding your survey, "Relationships of Stress Exposures to Health in Gulf War Veterans," this morning. Based on our conversation and the information provided, OMB review and approval is not necessary based on the conditions of the grant and because the Department is not "sponsoring" the collection of information, as defined in 5 CFR 1320. Thank you for the opportunity to review the survey instrument. Bob Cushing, DoD Clearance Officer

Ebert, Lori

To:

[NSCAW] Fairbank, John

Cc:

Ebert, Lori

Subject:

FW: Grant for Gulf War Illness Survey

E-mail message from Jim White, DoD Internal Reports Control to Dr. Robert Bray at RTI stating that DAMD17-98-1-8662 "Relationships of Stress Exposures to Health in Gulf War Veterans" is not subject to the provisions of DoD 8910.1-M, "DoD Procedures for Management of Information Requirements."

----Original Message----

From: White, Jim, CIV, WHS/DIOR [mailto:WhiteJ@osd.pentagon.mil]

Sent: Tuesday, April 11, 2000 11:25 AM

To: RMB@rti.org

Cc: Jeffery, Anne, CIV, WHS/DIOR; Cushing, Bob, CIV, WHS/DIOR; Elig, Tim

W.,, DMDCEAST

Subject: Grant for Gulf War Illness Survey

Dr Bray,

As a representative of a non-Government entity (Research Triangle Institute) you are not subject to the provisions of DoD 8910.1-M, "DoD Procedures for Management of Information Requirements." You will need to coordinate with the Defense Manpower Data Center and satisfy their documentation requirements in order to obtain the sample. If you need further assistance please contact me at 703-604-4582 or by electronic mail.

James A. White
DoD Internal Reports Control

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From: "Smith, Catherine A Ms USAMRMC" <Catherine.Smith@DET.AMEDD.ARMY.MIL>
  To: "'John Fairbank'" <jaf@psych.mc.duke.edu>
  Subject: RE: Duke & RTI IRB approvals of mods to Human Subjects Research P
               rotocol for DAMD17-98-1-8662
  Date: Mon, 18 Sep 2000 06:39:30 -0400
  X-Mailer: Internet Mail Service (5.5.2650.21)
 X-AntiVirus: scanned for viruses by AMaViS 0.2.0-pre6 (http://aachalon.de/AMaViS/)
 Dear Dr. Fairbank,
 Thank you for your response. Your protocol was approved on 15 September!
 You should be hearing soon from the contracting specialist who is Cheryl
 Lowery. Her phone number is 301-619-7150. Thank you for all your help and
 best wishes on your study!
 Catherine A. Smith
 Human Subjects Protectrion Specialist
 Regulatory Compliance and Quality
 U.S. Army Medical Research and Materiel Command
 ATTN: MCMR-RCO
 504 Scott Street
 Fort Detrick, MD 21702-5012
 fax: 301-619-7803
 ----Original Message----
 From: John Fairbank [mailto:jaf@psych.mc.duke.edu]
 Sent: Sunday, September 17, 2000 10:28 PM
 To: Smith, Catherine A Ms USAMRMC
 Subject: RE: Duke & RTI IRB approvals of mods to Human Subjects Research
 P rotocol for DAMD17-98-1-8662
 Dear Ms. Smith
 Thank you for your letter. The copy of the letter to Dr. Falletta, Chair
 of the IRB, from me that I faxed to you has the Duke IRB - stamp of
 approval for the revised protocol and revised consent forms. This is the
 cover letter to the revised protocol and the consent forms and is the
document that contains the Duke IRB stamp of approval. This is the
official Duke approval form from Dr. Falletta.
Thanks so much for your help. Please let me know if I can provide any
additional information. I look forward to the Army IRB's approval.
John Fairbank
>Dr. Fairbank,
>I just received the fax. Thank you. Could you fax me the cover page of
>protocol and consent form which has your IRB-stamp of approval? Then I can
>do the final approval. Thanks.
>Catherine A. Smith
>Human Subjects Protectrion Specialist
>Regulatory Compliance and Quality
>U.S. Army Medical Research and Materiel Command
>ATTN: MCMR-RCQ
>504 Scott Street
>Fort Detrick, MD 21702~5012
>fax: 301-619-7803
>----Original Message----
>From: John Fairbank [mailto:jaf@psych.mc.duke.edu]
>Sent: Wednesday, September 13, 2000 5:17 PM
>To: Smith, Catherine A Ms USAMRMC
>Cc: loe@rti.org
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APPENDIX E

Approvals from Institutional Review Boards of Duke University Medical Center and the Research Triangle Institute

- 1. Approvals for full study implementation
- 2. Approvals for modifications made to respond to U.S. Army Human Subjects review

DUKE UNIVERSITY MEDICAL INSTITUTIONAL REVIEW BOARD RESEARCH PROTOCOL

omplete and submit original and 2 copies	s to IRB (Room 106, Seeley (3. Mudd Bldg., Bax 2991)	15 days before schedule FAX# 687-4737	ed meeting.
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Research Triangle Institute P.O. Box 12194 Research Triangle Park, NC 27709-2194 Multiple Project Assurance No. M-1496

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL IRB # 03

PROJECT LEADER:	
Robert M. Bray	
TITLE: Relationships of Stress Exposures to	Health in Gulf War Veterans
SPONSOR AGENCY: US Army	PROTOCOL DATE: March 13, 2000
RTI PROJECT NUMBER: 7360	or PROPOSAL NUMBER:
NATURE OF REVIEW: (check one) FULL X EXPEDITED	EXEMPT
MEETING DATE: March 21, 2000	
CUB IECTS	REVIEW PRIOR TO INVOLVE MENT OF HUMAN E NEXT REVIEW PRIOR TO FULL IMPLEMENTATION .
Please note the following requirements:	
PROBLEMS OR ADVERSE REACTIONS: If proble adverse reactions occur as a result of this study,	ems in treatment of human subjects or unexpected you must notify the IRB Chairperson immediately.
CHANGES IN PROTOCOL: If there are significant notify the IRB Chairperson before they are imple	t changes in procedures or study protocol, you must mented.
RENEWAL: You are required to apply for renewa is active. Your next review date should be on or expires on March 21, 2001.	l of approval at least annually for as long as the study before March 21, 2001. IRB approval for thisproject
Steven Gurphisel IRB # 03 Chairperson	March 21, 2000 Date
Steven A. Garfinkel, Ph.D. Print or Type Name	
Copy of approved Informed Consent attached.	
cc: Project Leader	rowd

RTI.IRB 2/2000

Telephone (919) 687-4686 Facsimile (919) 687-4737

DATE:

September 5, 2000

TO:

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John M. Falletta, M.D., Chair, Medical Center IRB

FROM:

John A. Fairbank, Ph.D. Anhal Ail

SUBJECT: Expedited Review of Changes to Procedures for DUMC-IRB Registry No 000626-003R1—Relationships of Stress Exposures to Health in Gulf War Veterans

On March 7, 2000 the DUMC IRB approved the research and data collection protocol for Phase I (i e., the mail survey) of the U.S. Army Medical Research and Material Command (USAMRMC) funded study entitled "Relationships of Stress Exposures to Health in Gulf War Veterans." Duke University Medical Center (DUMC; J. A. Fairbank, PI) is the grantee for this study; Research Triangle Institute (RTI) serves as a subcontractor to DUMC. In the minutes of the June 2000 USAMRMC Human Subjects Review of this research the Army made several recommendations that to be fully addressed required minor modifications to the study procedures and materials. On August 14, 2000 I sent Catherine Smith at the USAMRMC a revised Human Subjects Protocol that included these modifications. On August 15, 2000 I received notification from Catherine Smith indicating that the Army was satisfied with these revisions and would approve the study once the Army received approvals from the DIMC and RTI IRBs for the

would approve the study once the Army received approvals from the DUMC and RTI IRBs for the revisions (with or without additional modifications as requested by the local IRBs). In accordance with 45 CRF 46.110 regulations concerning "minor modifications to an approved protocol" that "involve no more than a minimal risk", I am requesting an expedited review of these revisions as specified below.

The only significant changes to the procedures and materials for this study from those specified in the protocol approved by the DUMC IRB on March 7 result from a change in the incentive procedures. Although the budget for this mail survey of 10,000 Gulf War Veterans is such that cost of providing compensation to all respondents is prohibitive, the original protocol indicated that respondents who return the survey in a timely fashion would be entered into up to three drawings to win one of 10 cash prizes. However, the minutes of USAMRMC Human Subjects Review pertaining to this incentive procedure stated that "Active Duty military cannot be paid for their participation in research studies" Further correspondence with staff at the military Legal Affairs Office confirmed that Active Duty military personnel are not permitted to receive any form of compensation (including noncash incentives) for

Specifically, the protocol stated that "Respondents whose surveys are received within 6 weeks of the initial mailing (i.e., before the second mailing) will be eligible for two Grand Prizes of \$500. Respondents whose surveys are received within 12 weeks of the initial mailing (i.e., before the third mailing) will be eligible for four First Prizes of \$250. Respondents whose surveys are received within 16 weeks of the initial mailing (i.e., within 4 weeks of the third mailing) will be eligible for four Second Prizes of \$150 If a respondent is entered into a drawing and not selected, he or she will automatically be entered in the drawing for the next round of prizes. To preserve confidentiality, respondents' identification numbers, will be used to randomly select winners of these drawings."

participation in government-funded research unless such research involves a blood draw, which the Gulf War Veterans Health Survey does not.

In light of this regulation, in the revised USAMRMC Human Subjects Protocol submitted August 14, I proposed offering participation in the prize drawing only to potential respondents who were not currently on active duty (i.e., not on active duty when the sample frame is created) The USAMRMC Human Subjects Review Board is satisfied with this approach which I now present to the DUMC IRB for review. The available information suggests that a relatively small percentage of the study sample will be Active Duty military and that some form of incentive might increase response rates and thus the generalizability of the study findings. Although I realize that introducing even such a minor inequity among study respondents is not ideal, our study team believes that this is the best approach among those available to us and certainly preferable to excluding all Active Duty military from the study. To address this change in incentive procedures, our research team has drafted two versions of the study informational brochure and consent form (attached) These differ from the original versions and each other in that the prize drawing for timely response to the survey is described only in the materials prepared for potential respondents not currently on active duty. It is worth noting that prior to proposing this approach we confirmed that the Defense Manpower Data Center, who will be providing the sample frame for this study, could provide a variable which would specify whether or not each individual in the sample frame is currently on Active Duty.

There have been no other changes to the procedures for the Gulf War Veterans Health Survey since the study was approved by the DUMC and RTI IRBs. Minor changes to the study materials requested by the USAMRMC were as follows: (1) The addition to paragraph 2 of the consent form of the following sentence: "You only need to complete the enclosed questionnaire if you wish to be enrolled in this study;" and (2) Further specification in the consent form for respondents not on active duty of when the prize drawings would be held and how participants would be notified if they had won. (See paragraph 5 of informed consent letter for potential respondents not currently on active duty.)

Should you have additional questions about this matter, including the appropriateness of these changes for an expedited review, please feel free to contact the for additional information at 684-4686, ext. 265. Thank you for your time and assistance.

INSTITUTIONAL REVIEW BOARD

APPENDICES:

1 Draft Text For Pamphlet Describing Gulf War Veterans Health Survey

A. Pamphlet for Active Duty Military

B. Pamphlet for Gulf War Veterans Currently Not on Active Duty

2. Consent Form For Gulf War Veterans Health Survey

A. Consent Form for Active Duty Military

B. Consent Form for Gulf War Veterans Currently Not on Active Duty

3 DUMC and RTI IRB Approvals for the Gulf War Veterans Health Survey

4. US Army IRB e-mail message indicating approval of revisions pending DUMC- and RTI- IRB approvals of revisions

Research Triangle Institute P.O. Box 12194 Research Triangle Park, NC 27709-2194 Multiple Project Assurance No. M-1496

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL IRB # 03

PROJECT LEADER:
Robert M. Bray
TITLE: Relationships of Stress Exposures to Health in Gulf War Veterans
SPONSOR AGENCY: <u>US Army</u> SUBMISSION DOCUMENT DATE: <u>August 31, 2000</u>
RTI PROJECT NUMBER: 7360 or PROPOSAL NUMBER:
NATURE OF REVIEW: (check one) FULL EXPEDITED X EXEMPT
MEETING DATE: N/A
TYPE OF APPROVAL: PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS. PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION. FULL IMPLEMENTATION. RENEWAL. AMENDMENT: Two modifications to consent form letters to veterans dated August 10, 2000 and two modified brochures dated August 31, 2000.
Please note the following requirements:
PROBLEMS OR ADVERSE REACTIONS: If problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately.
CHANGES IN PROTOCOL: If there are significant changes in procedures or study protocol, you must notify the IRB Chairperson before they are implemented.
RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before March 21, 2001. IRB approval for this project expires on March 21, 2001.
Steven Farfuck IRB # 03 Chairperson September 13, 2000 Date
Steven A. Garfinkel, Ph.D. Print or Type Name
Copy of approved Informed Consent attached.
cc: Project Leader Office of Research Contracts: <u>Richard Strowd</u>

RTI.IRB 2/2000